Date: August XX, 2019
Olympus reference: 152P-FCA-0006

URGENT MEDICAL DEVICE SAFETY NOTICE

RE: Cautions on frayed forceps elevator wire and additional inspection instruction the frayed wire

Attention: Operating Room Manager, Risk Management Department and Reprocessing Units

	Model Name	**Serial number**
OLYMPUS DuodenoVideoscope	**TJF-160R, TJF-140R, JF-140R, TJF-240, JF-240**	All
OLYMPUS DuodenoFiberscope	**JF-1T40, JF-TE3**	All

Dear Health Care Practitioner:

Olympus has become aware of an issue that requires your attention. This Safety Notice pertains to the OLYMPUS Duodenovideoscopes and Duodenofiberscopes. The endoscopes are intended for use in endoscopy and endoscopic surgery within the duodenum.

Olympus has received complaints about fraying elevator wires of Olympus Duodenovideoscope JF-260V ,TJF-260V and TJF-160VR. Olympus is aware of adverse event complaints on the JF-260V and TJF-260V endoscopes. To date, a total of 12 cases have occurred in the world resulting in the inside patient's body and the finger of hospital staff member were injured by a frayed elevator wire with respect to the JF-260V / TJF-260V models.
Olympus has already issued a Field Safety Notification on the JF-260V, TJF-260V and TJF-160VR since January 2019 (Olympus reference #150P-FCA-0019) in order to enhance the inspection for the frayed wire prior to use.

The product mentioned above **(TJF-160R, TJF-140R, JF-140R, TJF-240, JF-240**, **JF-1T40 and JF-TE3)** have detachable distal end cover and opened forceps elevator wire at the distal end design similar to JF-260V / TJF-260V/TJF-160VR. Although there has been no complaints and reportable events on the injury related to the frayed forceps elevator wire associated with the subject devices since 2004 and the subject product have been already discontinued, there is a possibility that injury may occur by frayed elevator wire in the future.

In an effort to mitigate potential risk to patient and staff health, Olympus is undertaking this action to notify users about these complaints and the need for careful inspection of the endoscope prior to use in accordance with the instructions provided below.

Action Steps:
Our records indicate that your facility has purchased one or more subject endoscopes. **OLYMPUS requires that you take the following actions**:

Inspect your inventory for the referenced devices and identify any of the specified OLYMPUS models. Please maintain with your inventory the attached Instructions for Safe Use and conduct the following activities.

1. Please inspect the subject endoscopes prior to patient use as per the enclosed Instructions for Safe Use. We have added pictures and additional instructions on the enclosed Instructions for Safe Use to assist in performing this inspection.

2. Please note on the enclosed form that you have received this Safety Notice.
3. Fax the completed form to XXX-XXX-XXXX.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information such as other compatible endoscope accessories, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday till Friday or by e-mail at XXX.

Regards,

REPLY FORM – XXXXXXXXXX

OLYMPUS URGENT FIELD SAFETY NOTICE					
[Name & Address of Hospital/Medical Facility]					
[Dept/Attn]					
[**Date]**					
OLYMPUS Endoscopes affected Models (Please insert the quantities available in your facility in front of the Model Name)					

I herewith acknowledge the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of inspection of the Duodenovideoscopes and the Duodenofiberscopes prior and after every use.

Name (Signature) _____

Name (Print) _____

Position _____

Please fax this completed reply form to Olympus at [contact number] latest by XXXX

OLYMPUS®

CE 0197

Instructions for safe use

Name	Model
EVIS EXERA DUODENOVIDEOSCOPE	TJF-160R
EVIS DUODENOVIDEOSCOPE	TJF-140R, JF-140R, TJF-240, JF-240
OES DUODENOFIBERSCOPE	JF-1T40
DUODENOFIBERSCOPE	JF-TE3

The section below provides instructions and additional inspection points that need to be followed in connection with the forceps elevator wire of the endoscope described in “Inspection of the endoscope” of Chapter 3, “Preparation and inspection” in the Operation Manual.
Other parts of the instructions in Chapter 3, “Preparation and Inspection” are not changed. Refer to the Operation Manual of each specific endoscope including the case when any irregularity is suspected. Before using the endoscopes, read this instructions and the Operation Manual and the Reprocessing Manual carefully and follow the instructions. If an abnormality is detected before or during usage, or the equipment is malfunctioning, do not use the equipment and contact Olympus to request a repair.
No new repair parts and no repairs or service are available for some of the affected endoscope models listed above. Contact Olympus to discuss the options for an endoscope upgrade.

Cautions

WARNING

- The elevator wire at the distal end is damaged (broken, frayed, or bent), the damaged elevator wire may cause injury or pose an infection control risk when detaching of the distal cover or cleaning the endoscope. In this case, carefully detach the distal cover and perform cleaning.

CAUTION

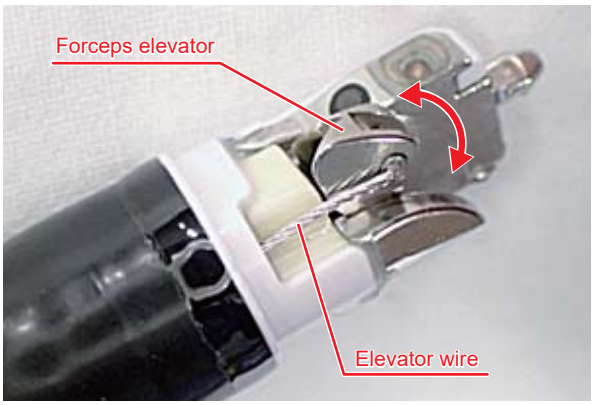
- If the elevator wire at the distal end is either damage broken, frayed or bent, the equipment may not function properly but and may also compromise patient operator or other medical personnel safety resulting in more severe equipment damage.
- When attaching the distal cover, make sure to confirm that the portion of the elevator wire at the distal end is not broken, frayed or bent. Otherwise, the broken elevator wire may cause injury. Also, if the broken elevator wire is deformed, it may compromise patient, operator or other medical personnel safety.
- Using a stiff brush or excessive force when brushing may scratch the distal end and result in water leakage; cause the elevator wire to come off the distal end, bend or kink the elevator wire so that the forceps elevator will no longer work.

Inspection of the elevator wire at the distal end

The qualified user should inspect the elevator wire at the distal end according to the following procedure.

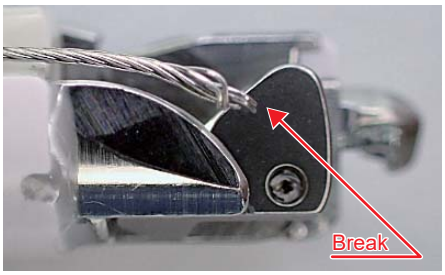
Visually confirm that the elevator wire at the distal end is not broken, frayed or bent, when moving the elevator control lever to make the forceps elevator “raise ↔ lower”.

■ “raise ↔ lower”

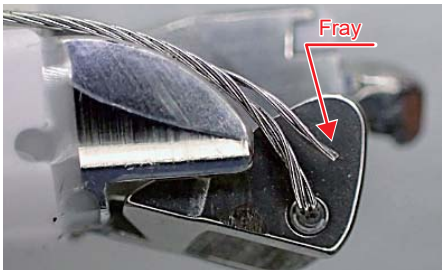


OK

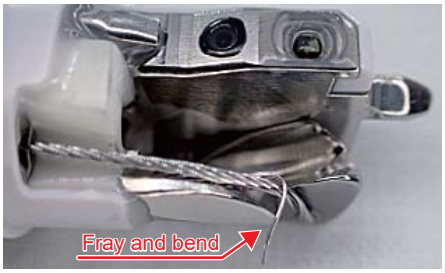
Not OK



Not OK



Not OK



Manufactured by

MANUFACTURER
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan Fax: (042)646-2429 Telephone: (042)642-2111

Distributed by

AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
OLYMPUS EUROPA SE & CO. KG
(Premises/Goods delivery) Wendenstrasse 14-18, 20097 Hamburg, Germany
(Letters) Postfach 10 49 08, 20034 Hamburg, Germany
Fax: (040)23773-4656 Telephone: (040)23773-0

KEYMED (MEDICAL & INDUSTRIAL EQUIPMENT) LTD.
KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, United Kingdom
Fax: (01702)465677 Telephone: (01702)616333

OLYMPUS MOSCOW LIMITED LIABILITY COMPANY
Elektrozavodskaya str. 27 bld.8, 107023 Moscow, Russia
Fax: (7)495-926-7072 Telephone: (7)495-926-7077

OLYMPUS AMERICA INC.
3500 Corporate Parkway, P.O. Box 610, Center Valley, PA 18034-0610, U.S.A.
Fax: (484)896-7128 Telephone: (484)896-5000

OLYMPUS LATIN AMERICA, INC.
5301 Blue Lagoon Drive, Suite 290 Miami, FL 33126-2097, U.S.A.
Fax: (305)261-4421 Telephone: (305)266-2332

OLYMPUS (BEIJING) SALES & SERVICE CO., LTD.
A8F, Ping An International Financial Center, No. 1-3, Xinyuan South Road,
Chaoyang District, Beijing, 100027 P.R.C.
Fax: (86)10-5976-1299 Telephone: (86)10-5819-9000

OLYMPUS AUSTRALIA PTY LTD
3 Acacia Place, Notting Hill, VIC 3168, Australia
Fax: (03)9543-1350 Telephone: (03)9265-5400

OLYMPUS SINGAPORE PTE LTD
438B Alexandra Road #03-07/12, Alexandra Technopark Blk B, Singapore 119968
Fax: 6834-2438 Telephone: 6834-0010

OLYMPUS KOREA CO., LTD.
(Seocho-dong, Majestar City Tower One), 2F & 3F, 12, Seocho-daero 38-gil,
Seocho-gu, Seoul, 06655, Republic of Korea
Fax: (02)6255-3210 Telephone: 1544-3200

RC7216 01
Printed in Japan 2019XXXX *0000